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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,345	09/27/2000	Ira H. Pastan	15280-339PC	2468

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,345

Applicant(s)

PASTAN ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-96, 113-121 and 123-165 is/are pending in the application.
- 4a) Of the above claim(s) 33-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113-121 and 123-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-32, 97-112 have been canceled in the response of 10/28/02.
Claims 113-165 were added in the response of 10/28/02.
Claim 122 was canceled and claims 113-115, 117-118, 120-121, 135-136, 140-141, 145-147, 149-150, 154-155, 158-159, 162-165 were amended in the amendment of 12/4/02
2. Claims 33-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 12.
3. Claims 113-121, 123-165 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action
5. The following Office Action contains some NEW GROUNDS of rejection.

Sequence Requirements

6. This application contains Figure 1 which contains a sequence that is encompassed by the sequence rules, however, the sequence in Figure 1 does not have a proper SEQ ID NO. The specification discloses the sequence in Figure 1 as SEQ ID NO:5, however, as stated in the response filed 12/4/02 figure 1 contains a isoleucine at position 21 whereas SEQ ID NO:5 has a leucine at position 21. This statement appears to be wrong because Figure 1 has a leucine at position 21 and SEQ ID NO:5 has a

isoleucine at position 21. Never the less there appears to be a discrepancy between the figure and the SEQ ID NO. As such this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth above.

Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

APPLICANT IS GIVEN THE TIME ALLOTTED IN THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Rejections Withdrawn

7. The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

9. All previous art rejections have been withdrawn in view of the amendments to the claims.

Response to Arguments

10. The rejection of newly added claims 113-121, 123-144, under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is maintained.

The response filed 10/28/02 has been carefully considered but is deemed not to be persuasive. The response states that with respect to antibodies that have a VH or a VL of SEQ ID NO:5, but not both chains, the Action argues that the specification does not enable such because the art teaches that formation of an intact antigen binding site requires the association of a heavy chain and a light chain and specific CDRs (see page 16 of the response of 10/28/02) and the response cites publications that teach a VH-

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PE33 construct that bound antigen (see page 17 of response of 10/28/02). In response to this argument, while it may be true that the Kuan and Pastan PNAS paper does teach a VH binding to LewisY antigen, the claims in the rejection do not recite the antigen to which the antibody binds and therefore one skill in the art would not know which antigen the antibody binds to or for claims 135 and 140 which heavy or light chain to pair with the light chain and heavy chain to obtain an antigen binding pair because the antigen is not recited.

This rejection may be obviated by adding to the claims (claims 113, 135, and 140) that the antibody specifically binds mesothelin or that the antibody is "an isolated anti-mesothelin antibody".

The following are some NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

11. Claims 113-121, 123-165 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 113-114, 118, 135-136, 140-141, 145-146, 150, 145-155, 158-159, 162-163, and 165 have been amended to recite "Figure 1 (SEQ ID NO:5)". As discussed above in the sequence requirements there appears to be a discrepancy in the Figure 1 sequence and the SEQ ID NO5 in the sequence listing. Figure 1 has a leucine at position 21 and SEQ ID NO:5 has a isoleucine at position 21. When the sequence

listing was supplied subsequent to filing of the application (see paper # 8 of 8/6/01, filed 8/3/01) the response stated that support for the "I" at position 21 is supported by the sequence of the DNA of SEQ ID NO:1 which was in the GenBank Accession Number AF035617 where the nucleotide at position 61-63, "ata" encodes "I" therefore the change in the "I" for "L" at position 21 does not introduce new matter (see page 3 of response filed 8/6/01). In response to these arguments, upon review of the GenBank Accession Number AF 035617 it is not clear when this sequence was deposited or if subsequent sequences were replaced by such sequence. As such it is not clear if the sequence was deposited before the effective filing date of the application which claims priority as a 371 to PCT US98/25270 and 60/067175. Neither of these applications list a sequence with a "I" at position 21 in Figure 1. Therefore it is not clear where support is found for the change.

Applicant is invited to clarify the record as far as priority and the deposit of the DNA in Accession number AF 035617. Due to this discrepancy it appears that there is no support in the application or the claims as originally filed.

12. Claim 120 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 120 was amended to recite a dsFv having a VL containing a cysteine at position 42, 43, 44, 45, 46, 98, 99, 100, or 101 as determined by the numbering published by Kabat and Wu and a VH containing a cysteine at recited positions. The response filed 12/04/02 states that support for the amendment can be found at page 8, lines 24-5 with incorporation of patent 6,147,203. This response has been carefully considered but is deemed not to be persuasive. The incorporation incorporates the generic term of dsFv fragments but does not state cysteines at specific locations as indicated in the claim. Thus, there is no support for a dsFv with the specified cysteines at the recited locations. Applicant is required to provide specific support for the claimed limitation in the specification as originally filed or remove it from the claim.

Conclusion

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of

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this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written over the typed name.